UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

TAMARA J. TOWNSEND, Plaintiff v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants	Case No.: 2:20-cv-01984-APG-DJA **Order Granting in Part Motion to Exclude General Causation Opinions of Dr. Wasserman** [ECF No. 75-1]

This case is one of thousands that were joined in multidistrict litigation (MDL) in the United States District Court for the Southern District of West Virginia. That court conducted the MDL litigation in waves, with this case being in wave 12. The case was transferred to this court from the MDL court with several motions pending, including plaintiff Tamara Townsend's motion to limit the general causation opinions of the defendants' expert, Dr. Richard Wasserman.

Townsend contends I should exclude Dr. Wasserman because he testified that he does not believe expert testimony is helpful and he stated he was "making it up" as he went. Alternatively, she contends he is not qualified or his opinions are unreliable regarding the physical properties of polypropylene mesh and its effects in the body, the warnings in the instructions for use (IFU), and whether there is a clinically significant difference between laser and mechanically cut mesh. The defendants oppose. The parties are familiar with the facts so I do not repeat them here except where necessary. I grant the motion in part.

I. ANALYSIS

I adopt Judge Goodwin's prior articulation of the standard for reviewing motions challenging expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow*

Pharmaceuticals, Inc., 509 U.S. 579 (1993). *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701-02 (S.D. W. Va. 2014).

A. Dr. Wasserman's Testimony

Townsend argues that Dr. Wasserman testified that he would not put too much weight on the opinion of one person. She asserts that the jury therefore should not rely on his opinion, which is simply the opinion of one person. She contends he also repeatedly stated that he was "making it up as I go," "guessing," and "just kind of making stuff up." And she asserts that Dr. Wasserman has no specialized knowledge or experience to support his opinions because he does not currently use the TVT products, has never published a peer-reviewed article on mesh slings or polypropylene mesh, could not define the standard of care, and contradicted himself on whether physicians who use the Burch procedure perform outside the standard of care but do not commit malpractice.

The defendants respond that Townsend takes Dr. Wasserman's testimony out of context and that he was merely stating that, like any scientific expert, he would not rely on one individual's statement and instead would rely on an array of reliable sources. They also contend Dr. Wasserman's statements about guessing were in response to Townsend's counsel asking hypothetical questions because the hypotheticals were not supported by the scientific literature or Dr. Wasserman's own clinical experience. They also contend Dr. Wasserman has performed thousands of sling procedures over the past 13 years, including hundreds that involve TVT products, so the fact that he does not currently use TVT products does not undercut his expertise.

Townsend's critiques of Dr. Wasserman's testimony go to its weight, not its admissibility. Dr. Wasserman explained that he would not put too much weight on the opinion of one person because he rests his opinions on evidence such as intermediate and long-term

studies, systematic reviews, and meta-analyses. His statements about guessing and making things up were in response to hypothetical questions posed by counsel, he explained that he was guessing because the question posed did not match his experience with the mesh or the scientific literature, or he disagreed with terminology (like what constitutes a mini-sling). *See* ECF No. 75-1 at 210-11, 235, 246-48, 257.

Being published or currently using the product at issue are not prerequisites to expert testimony. Dr. Wasserman is a urogynecologist and pelvic reconstructive surgeon. *Id.* at 9. He is board certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. *Id.* Over the past 13 years as a pelvic surgeon, he has performed thousands of retropubic mid-urethral sling procedures and hundreds of trans-obturator mid-urethral sling procedures, including procedures involving various TVT devices. *Id.* He also has reviewed medical literature in these areas to support his opinions. *Id.* at 15. Dr. Wasserman is qualified to opine on mid-urethral sling procedures and the TVT devices.

As for his testimony on the standard of care, Dr. Wasserman stated the standard was a mid-urethral sling but that physicians could opt for the Burch procedure for their patients. *Id.* at 115-18. Any contradiction can be explored through cross examination, but it is not a basis to exclude his testimony. I therefore deny this portion of Townsend's motion.

B. Opinions on Mesh Physical Properties

Townsend contends Dr. Wasserman should not be allowed to opine on the physical properties of mesh because he is not a chemical engineer or surgical pathologist, rarely reviews histopathologic slides, and has no background in polymer chemistry. Townsend contends he could not identify the type of polypropylene used in the product he currently uses or in the defendants' products. And she contends he has done no research on polypropylene, published no

opinions on it, has never tested the mesh's stiffness, and has never designed a medical device. She also contends that the only support he identified for his opinion that Prolene mesh is safe and effective was the affidavit of an Ethicon employee. Finally, she argues that he declined to explain why he rejected the possibility of particle loss occurring in the packaging, and he could not cite any evidence to support his conclusion that the mesh is not cytotoxic when Ethicon's own tests showed mesh is cytotoxic.

The defendants respond that the MDL court has allowed urogynecologists like Dr. Wasserman to testify on the physical properties of mesh. They argue that Dr. Wasserman's training, review of medical literature, and clinical experience qualify him to testify regarding the physical properties of TVT mesh devices.

Dr. Wasserman's testimony that that he is not a chemical engineer or an expert in polymer chemistry is not dispositive. Nor is his failure to conduct stiffness tests, research polypropylene, or design a medical device. Courts in similar cases have found that urologists or urogynecologists with years of experience related to implanting, revising, or removing mesh, and who rely on supporting scientific literature, are qualified to opine on polypropylene mesh. *See Foreman v. Bos. Sci. Corp.*, No. 2:13-cv-15591, 2016 WL 3039895, at *7-8 (S.D. W. Va. May 27, 2016); *Trevino v. Bos. Sci. Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *5 (S.D. W. Va. May 19, 2016); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 579-80 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014). I agree. "Any gaps in [the doctor's] knowledge go to his credibility, not his admissibility as an expert." *Foreman*, 2016 WL 3039895, at *7.

In his report, Dr. Wasserman stated that the TVT devices were made of Prolene polypropylene mesh, that the Prolene material was developed in the 1960s, and that the FDA approved it as safe and effective in 1969 for use in the human body. ECF No. 175-1 at 11. The

only support he identified in his report for the statement that the FDA approved it in 1969 was the affidavit of an Ethicon employee.[1] *Id.* at 11 n.8; *see also id.* at 220-21. However, elsewhere in his report, Dr. Wasserman stated that Prolene "has been extensively used in surgeries for more than 50 years and is known to be well-tolerated by the human body." *Id.* at 20. He bases that opinion on "a significant body of Level 1 evidence supporting the safety and efficacy of the devices." *Id.* And he cites that evidence throughout his report. His statement that the FDA approved polypropylene mesh as safe and effective in 1969 and the basis for that statement are matters for cross examination, not exclusion of his opinions.

Townsend argues that Dr. Wasserman did not explain why he rejected the possibility of particle loss occurring in the packaging. However, he stated in his report that he has "seen no evidence in [his] practice or in the published literature indicating that particle loss occurs in the body." *Id.* at 21; *see also id.* at 244-45, 250 (stating he had never encountered loose particles, has not seen evidence of particle loss, and any particle loss was not "clinically relevant"). He also stated that even if particle loss occurs, "there is no reason to believe that would cause complications, as the particles lost would be the same Prolene material" that he opines is safe. *Id.* at 21. Townsend may confront Dr. Wasserman at trial with internal Ethicon documents "indicating that particles can migrate through the vaginal tissue and cause pain" and that some devices had been returned to Ethicon because there were loose particles in the package, just as she did at his deposition. *Id.* at 244-45. Any inconsistency between Dr. Wasserman's experience and review of the scientific literature versus internal Ethicon documents goes to the weight of his testimony, not its admissibility.

[1] Neither party provides the affidavit, so it is unclear whether the affidavit identified a source for that statement.

Likewise, Dr. Wasserman explained why he thinks the mesh is not cytotoxic. He stated that the literature shows that over 99 percent of patients do not have erosion or exposure, and he would expect a significantly higher percentage of complications if the mesh were cytotoxic. *Id.* at 253-57, 259-60. He acknowledged that tests in the 1990s concluded the mesh was "markedly or moderately cytotoxic," but he did not "place too much value on those based on the current body of evidence which says that it is not cytotoxic." *Id.* at 257-58. Townsend's challenge goes to the weight of his testimony, not its admissibility. I therefore deny this portion of Townsend's motion.

C. Laser versus Mechanically Cut Mesh

Townsend argues that I should exclude Dr. Wasserman's opinion that there is no clinically significant difference between the two methods of cutting mesh because Dr. Wasserman relies on his own belief about complication rates in his practice, but there is no evidence he reliably measured those complication rates. She also contends that his definition of a complication is itself suspect because he has never reported a complication to the FDA even when he has had to perform a mesh revision surgery. Finally, she asserts that his only other support for this opinion is a general reference to "the literature," without any further explanation. The defendants respond that Dr. Wasserman supports his decision with articles summarizing studies on this issue.

To the extent Dr. Wasserman's opinion is based on a review of scientific literature, he identifies support for it in his report. *Id.* at 21, 23. Townsend does not explain why the literature he cites is an insufficient basis for his opinion.

However, Dr. Wasserman cannot opine that he has "not seen a clinically significant difference in the rate of complications" between the two types of cutting methods because there

is insufficient evidence that he reliably calculated complication rates based on his own clinical experience. *Id.* at 23. Dr. Wasserman testified that although he used both types, he could not quantify how many mechanical versus laser cut mesh slings he had used. *Id.* at 191-92. And he had not done a formal analysis of complication rates between the two in relation to his clinical practice. *Id.* at 192.

There is no evidence Dr. Wasserman reliably identified what constitutes a complication. He cited literature comparing complication rates for various procedures that categorized as a complication the need to return to the operating room. *Id.* at 17-18. But he testified that despite doing revision surgeries for mesh complications, he did not report those to the FDA as adverse events, and he did not consider surgical revision or excision to be a serious complication. *Id.* at 163-64, 165-66. Dr. Wasserman's potentially selective view of what constitutes a complication, combined with his lack of a scientific method for determining complication rates, renders his opinion comparing complication rates based on his clinical experience unreliable. I therefore exclude it. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016) (excluding a physician's complication rate opinion that was based on "estimates and not from accumulated data or patient records").

D. Warnings

Townsend argues Dr. Wasserman's testimony about warnings should be excluded because he testified the IFUs have no value to physicians, he does not rely on them, and he disagrees with the FDA's standards for warnings. She also argues he has no expertise related to warnings. The defendants respond that Dr. Wasserman is qualified to testify regarding what risk exists and whether they are listed in the IFU.

"While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *2 (S.D. W. Va. Aug. 30, 2016); *see also Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 551 (S.D. W. Va. 2014), *as amended* (Oct. 29, 2014) (excluding a physician opinion on what information a product manufacturer should have included in its directions for use because the doctor never drafted a warning and had no experience with warnings beyond that of physicians in general). Dr. Wasserman does not have such expertise. *See* ECF No. 75-1 at 139. Consequently, he may not opine on whether it is "unnecessary" for the IFUs to contain information about complication risks. *Id.* at 24. However, as an experienced urogynecologist, he may testify about the risks commonly known to urogynecologists and whether those risks appear in the IFUs.

II. CONCLUSION

I THEREFORE ORDER that the plaintiff's motion to limit the general causation opinions of Dr. Richard Wasserman **(ECF No. 75-1) is GRANTED in part**. Dr. Wasserman may not opine that there is no difference in complication rates between laser and mechanically cut mesh based on his clinical experience. Additionally, he may not opine on whether it is "unnecessary" for the instructions for use to contain information about complication risks. The motion to exclude is denied in all other respects.

DATED this 14th day of April, 2021.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE